

**REMARKS**

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1-2 and 24 under 35 U.S.C. § 102(b) as anticipated by Sim et al., Molecular and Biochemical Parasitology 34:127-134(1989) ("Sim") is respectfully traversed.

Sim does not disclose an isolated nucleic acid molecule encoding a Plasmodium falciparum chitinase. As defined in the present specification on page 14, lines 26-30, isolated refers to nucleic acid which has been separated from an organism in a substantially purified form (i.e. substantially free of other substances originating from that organism) and to synthetic nucleic acid. Sim does not disclose an "isolated" nucleic acid. It is the position of the U.S. Patent and Trademark Office ("PTO") that the claims are read broadly. However, as specifically stated in Manual of Patenting Examining Procedure ("MPEP") 2173.05(a), the meaning of a term should be apparent from the prior art or from the specification (emphasis added). The claims should be given the broadest reasonable interpretation consistent with the specification. (Id.) (emphasis added). When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning. (Id.) As clearly stated in the specification "isolated" refers to a nucleic acid which has been separated from an organism in a substantially purified form. Accordingly, Sim which does not disclose an "isolated" nucleic acid, cannot anticipate the claims of the present application. The

rejection, therefore, should be withdrawn.

The rejection of claims 1-3, 6-12 and 24 under 35 U.S.C. § 102(b) as anticipated by Vinetz et al. PNAS 96:14061-14066 (1999) ("Vinetz") is respectfully traversed. Vinetz was published in the November 23, 1999, edition of PNAS. The present application was filed on May 26, 2000, claiming priority to U.S. Provisional Patent Application Serial Nos. 60/136,508 and 60/180,051, filed May 28, 1999 and February 3, 2000, respectively. As indicated on page 2 of the outstanding office action, the present application has a priority date of May 28, 1999. Claims as presently pending are entitled to this priority date. Accordingly, Vinetz is not available as prior art against the claims of the present application. Therefore, the rejection is improper and should be withdrawn.

The rejection of claims 1-12, 23, 24 and 46 under 35 U.S.C. § 112 (first paragraph) for lack of written description is respectfully traversed in view of the above amendments.

The rejection of claims 1-12, 23, 24 and 46 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed in view of the above amendments.

The rejection of claim 23 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed in view of the above amendments.

The present application, as filed, indicates to one of ordinary skill in the art sufficient guidance and direction to make and use an isolated polynucleotide encoding a plasmodium falciparum where the polypeptide has at least 90% amino acid identity with SEQ ID NO:3. In particular, on page 17, line 1 to page 20, line 3 of the present specification, methods of determining amino acid identity and sequence homology are defined. One of ordinary skill in the art, using the information contained in the present specification, as

filed, could without undue experimentation determine whether two amino acid sequences, when optimally aligned, have amino acid identity of a particular percentage (See specification, pg. 19, lines 1-14). Further, one of ordinary skill in the art could, without undue experimentation make such polypeptides. It is well within the ordinary skill in the art to make conservative substitutions while retaining the functional properties of the polypeptide. It was well within the level of skill in the art to replace one amino acid with a substitute amino acid having similar chemical properties such as charge or polarity to retain the properties of the protein. Further, it was well within the level of skill in the art to test the proteins for the properties of the signal peptide without undue experimentation.

For example, multiple amino acid substitutions can be made and tested using known methods of mutagenesis and screening. These methods, known prior to the filing date of the present application, relate to procedures for simultaneously randomizing two or more positions in a peptide, selecting for functional peptides and then sequencing the mutagenized polypeptides to determine the spectrum of allowable substitutions at each position. Other known methods for determining amino acid substitutions include phage display or region-directed mutagenesis. These mutagenesis methods can be combined with high-throughput screening methods to detect the activity of cloned, mutagenized proteins in host cells. Mutagenized DNA molecules that encode active proteins can be recovered from the host cells and rapidly sequenced using modern equipment. These methods allow the rapid determination of the importance of individual amino acid residues in a peptide of interest. Thus, one of ordinary skill in the art would not have to unduly experiment to produce the claimed

invention based on the information provided in the present application.

It is the PTO's position that it is unclear what sequences are embraced by the claim (outstanding office action, page 6, paragraph 8). As discussed above, it was well within the ordinary skill of the art, at the time the application was filed, to make, without undue experimentation, the claimed sequences, i.e. those having 90% sequence identity using the methods set out in the specification. Thus, those skilled in the art would not be at all unclear as to what the claims cover. The PTO also indicates that the specification fails to teach what critical nucleic acids can be modified (outstanding office action, page 8). Applicants assert that such disclosure is not required. In order for the application to be enabling, the specification must teach one skilled in the art how to make the full scope of the invention (MPEP 2164.01(a)). A working example or reduction to practice is not required (MPEP 2164.02). Some experimentation may be required to practice the invention, as long as the experimentation is not "undue" (MPEP 2164.06). A extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance (Id.) A considerable amount of experimentation is permissible, if it is merely routine (Id.). Accordingly, the one of ordinary skill in the art (who routinely modify amino acids in a polypeptide and test to determine if the polypeptide has retained the biological activity), with the information contained in the application as filed, were enabled to practice the full scope of the invention.

The rejection of claim 46 under 35 U.S.C. § 112(second paragraph) for indefiniteness is respectfully traversed in view of the above amendments.

The rejection of claim 23 under 35 U.S.C. § 112(second paragraph) for indefiniteness is respectfully traversed in view of the above amendments.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

August 21, 2003  
Date

Karla M. Weyand  
Karla M. Weyand  
Registration No. 40,223

Rogalskyj & Weyand, LLP  
P.O. Box 44  
Livonai, New York 14487-0087  
Tel: 716-626-5380  
Fax: 716-626-5384

I hereby certify that this document is being deposited with the U.S. Postal Service as first class mail on 8/21/03 under 37 CFR 1.8 and is addressed to the Commissioner for Patent, PO Box 1450, Alexandria, VA 22313-1450

Karla M. Weyand  
Signature of Person Mailing Correspondence

Karla M. Weyand  
Typed Name of Person Mailing Correspondence